FEB - 7 2001

Section 1 D: Summary of Safety and Effectiveness for 4C®-ES Cell Control

1.0 General Information

Device Generic Name(s):	Hematology Quality Control Mixture
Device Trade Name(s):	4C®-ES Cell Control
Device Classification:	Class II
Applicant Name and Address:	Beckman Coulter, Inc. Cellular Analysis Division 11800 SW 147 Avenue Miami, FL 33196-2500
Date:	January 5, 2001

2.0 Legally Marketed Device(s)

The modified 4C® Cell Control claims substantial equivalence to the 4C® PLUS Cell Control, currently in commercial distribution

FDA 510(k) Number: K955016

3.0 Device Description

The product is a hematology quality control mixture intended to be used with automated cell counters and differential cell counters. 4C®-ES Cell Control is prepared from stabilized human blood so that repeated measurements by an automated cell counter, or differential cell counter, can be made to monitor instrument daily performance. 4C®-ES Cell Control consists of treated, stabilized human erythrocytes, a stabilized platelet sized component, and fixed erythrocytes that simulate leucocytes.

- The Coulter automated hematology analyzers utilizing 4C®-ES Cell Control include the ONYX™ Analyzer, ONYX with Autoloader Analyzer, MD™ Series Analyzers , MD II Analyzer, Ac•T™ 8/10 Analyzer, Ac•T diff™ Analyzer, Ac•T diff2™ Analyzer, JT™ Analyzer, JT2 Analyzer, JT3 Analyzer and T Series Analyzers. Each is an automated hematology analyzer capable of supplying a complete blood cell analysis; some models are capable of additionally performing a differential leucocyte cell count.

- COULTER ISOTON® III diluent is a buffered, isotonic solution containing Sodium Sulfate Anhydrous (9.72 g/L), Sodium Chloride (4.0 g/L), Dimethylolurea (1.0 g/L), and Procaine HCL (0.11 g/L) . Intended for use as a diluent for counting and sizing blood cells on COULTER® Hematology Analyzers.

- ISOTON® 3E diluent is a buffered, isotonic solution containing Sodium Sulfate Anhydrous (9.84 g/L), Sodium Chloride (4.0 g/L), and Procaine HCL (0.11 g/L) . Intended for use as a diluent for counting and sizing blood cells on COULTER® Hematology Analyzers.

- ISOTON® 4 diluent is a buffered, isotonic solution containing Sodium Sulfate Anhydrous (12.85 g/L), Sodium Chloride (0.6 g/L), Tetracaine HCL (0.02 g/L), and Imidazole (3.5 g/L) . Intended for use as a diluent for counting and sizing blood cells on COULTER® Hematology Analyzers.

- Lyse S® 4 lytic agent consists of quaternary ammonium salts (5 - 80 g/L), Sodium Sulfite (1- 5 g/L). Intended for the simultaneous quantitative determination of hemoglobin and for leukocyte counting and sizing on COULTER® Hematology Analyzers.

- Lyse S® III diff lytic agent consists of quaternary ammonium salts (35 - 50 g/L), isopropanol (11 - 14 g/L) and potassium cyanide (0.3 g/L). Intended for the simultaneous quantitative determination of hemoglobin and for leukocyte counting and sizing on COULTER® Hematology Analyzers.

4.0 Principle of Method:

4C®-ES Cell Control is prepared from stabilized human blood so that repeated measurements can be made to monitor performance of the instrument system. ASSIGNED VALUES are determined on validated systems using specific Beckman Coulter reagents. ASSIGNED VALUES are confirmed by multiple analysis of the control product.

5.0 Indications for Use:

4C®-ES Cell Control is a hematology quality control material used to monitor the performance of Beckman Coulter instruments listed in the TABLE OF EXPECTED RESULTS and with the specific Beckman Coulter reagents, ISOTON® III diluent / Lyse S® III Diff Lytic reagent.

Future commercialization will add ISOTON® 3E diluent as well as ISOTON® 4 diluent /Lyse S® 4 Lytic reagent to the indications for use.

6.0 Description of the modification:

The currently marketed COULTER 4C® PLUS Cell Control media formulation was modified to achieve an extended shelf life stability. The buffered anti-microbial media with stabilizers was changed from a phosphate-buffered saline at pH 6.7 to an EDTA/ imidazole buffer at pH 6.3. The same level of cellular components was maintained with no change to the function, storage conditions or intended use of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Stan Sugrue, Ph. D.
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 S. W. 147th Avenue
Miami, Florida 33196-2500

Re: K010064
Trade Name: Beckman Coulter 4C®-ES Cell Control
Regulatory Class: II
Product Code: JPK
Dated: January 5, 2001
Received: January 8, 2001

Dear Dr. Sugrue:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 1C: INDICATIONS FOR USE

510(k) Number (if known): ~~Not assigned~~ K010064

Device: 4C®-ES Cell Control

Indications For Use:

4C®-ES Cell Control is a hematology quality control material used to monitor the performance of Beckman Coulter instruments listed in the TABLE OF EXPECTED RESULTS and with the specific Beckman Coulter reagents, ISOTON® III diluent /Lyse S® III Diff Lytic reagent.

Future commercialization will add ISOTON® 3E diluent as well as ISOTON® 4 diluent /Lyse S® 4 Lytic reagent to the indications for use.

21 CFR 864.8625 Hematology Quality Control Mixture

A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count (WBC), red cell count (RBC), platelet count (PLT), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maglen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010064

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)